Medical Devices Regulatory Developments

Neil Adams, Operations and Delivery Director, BSI Medical Devices

4 November 2014
Overview

• European Commission’s Position of 14 October 2014
• Impact of the Immediate Actions after the PIP Scandal
• Impact of Proposed Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR): look at Commission examples
• Current Understanding of Regulatory Timetable
New EU legislation on Medical Devices

Erik Hansson
Deputy Head of Unit
European Commission
DG Health and Consumers
Presentation

- Drivers for change
- Commission proposals
- State of play in negotiations
- What do we do in the meantime?
Context

- Medical devices = essential for healthcare
- Medical devices sector = growth and competitiveness

European Union

One of the largest market

Some of the biggest companies

Ecosystem of SMEs / micro-enterprises
EU regulatory framework
- drivers for change

- Three directives transposed into national legislation based on common EU regulatory principles ("the New approach")
- From 12 to 33 countries - divergences in application and shortcomings in coordination
EU regulatory framework
- drivers for change (continued)

➢ Technical and healthcare developments
  ✓ Scientific and technological advances,
  ✓ More focus on prevention, early diagnosis, self-monitoring and cost-effectiveness
  ✓ Evolving knowledge and expectations

➢ Globalisation

➢ Public expectations following the PIP breast implants scandal
Revision of the legislation - background

➢ Public consultation launched in 2008
➢ Build on the strengths…
   ✓ Balance between pre- and post-market control
   ✓ Flexible - Supportive to innovation
   ✓ High safety levels
   ✓ Rapid access to market - Cost-effective and SME friendly

➢ … but adapt and improve
Revision of the legislation

26 September 2012:

- Commission proposal for a Regulation on medical devices
- Commission proposal for a Regulation on in vitro diagnostic medical devices
Revision of the legislation (continued)

- Aims at solving problems relating to:
  - Scope of the legislation
  - Governance of the system and transparency
  - Obligations of notified bodies
  - Clinical evaluation
  - Risk classification and safety and performance requirements
Revision of the legislation (continued)

✓ Obligations of economic operators
✓ Vigilance and market surveillance
✓ Eudamed
✓ Traceability of medical devices

➢ High priority for European Commission
Proposed transition periods:
  – Three years (MD)
  – Five years (IVD)
Revision of the legislation (continued)

European Commission
Proposes legislation

European Parliament
Proposes amendments

Council of the EU
Proposes amendments

Negotiation
Example of issue debated:
Pre-market control of high-risk devices

✓ Proposals made by the European Parliament: case-by-case assessment by the Medical Devices Coordination Group (‘MDCG’), assisted by a committee of scientific experts, focused on clinical aspects.

✓ Divergent positions of Member States.

✓ Commission: scrutiny mechanism important.
Example of issue debated: Notified bodies

- **Parliament and Council**: good proposals to strengthen the designation, monitoring and functioning of notified bodies.
- **Parliament**: separate designation of "Special Notified Bodies" competent for high-risk devices by the European Medicines Agency (‘EMA’).
- **Commission**: need to **carefully assess** the added value of EMA involvement, as well as the necessary resources and financing.
Example of issue debated: Reprocessing of single-use medical devices

✓ Proposals made by the European Parliament:
  • All medical devices are considered suitable for reprocessing and reusable;
  • Reprocessor must provide scientific evidence;
  • Commission to adopt standards for reprocessing;
  • Possibility for Member States to ban the practice on their territory;

✓ Diverging views between Member States

✓ Commission: Commission proposal balanced approach
Example of issue debated: Borderline products

✓ Case C-109/12, Laboratoires Lyocentre v Lääkealan turvallisuus, 3 October 2013:
the qualification of a product as a medical device in one Member State does not preclude it from being qualified, in another Member State, as a different product;

✓ Elements in the COM proposals aiming to ensure a more uniform implementation of the legislation:
  • the Commission may decide, by implementing acts;
  • group of experts;
  • classification rule 21
What do we do in the meantime?
Plan for immediate actions after PIP scandal

- Objective: strengthen controls on medical devices under the current regulatory system

- 4 pillars:
  - Functioning of notified bodies (NB)
  - Market surveillance
  - Coordination in vigilance and market surveillance
  - Communication and transparency
Plan for immediate actions after PIP scandal (continued)

Achievements:

✓ Re-assessment of qualifications and scope of activities of NBs
✓ Voluntary and mandatory joint audits of NBs
✓ 2 Commission acts
  • Criteria to be met for the designation of NB
  • Items to be verified by NB during an audit
✓ Monthly vigilance teleconferences
Plan for immediate actions after PIP scandal (continued)

- Achievements:
  - Analysis of trends on incidents
  - Commission Recommendation on traceability
  - Dialogue with Member States on registers
  - Report from Member States on market surveillance activities
Commission Staff Working Document on the Implementation of the Joint Plan for Immediate Actions under the existing Medical Devices legislation and further steps

Deepening:
- Market surveillance
- Co-ordination and communication
- Use of registers
- Trend detection
- Peer training

Supported by Ministers in the EPSCO Council 20 June 2014
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Overview

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## Impact of Immediate Actions

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| Re-assessment of qualifications and scope of activities of NBs        | • NBs submitted to CAs the CVs of all technical experts for high risk devices  
• Reduced scope for some NBs?                                         |
| “Voluntary” Joint Audits of NBs by Designating Authority, Commission (FVO) plus two other CAs | • NBs and Designating Authorities under scrutiny  
• Highlights different approaches in Member States  
• Some Pain and Some Gain                                               |
| Monthly Vigilance Teleconferences                                      | • Increasing number of COEN requests  
• More open COEN requests requiring detailed follow up }
Impact of Commission Implementing Regulation 920/2013 on the designation and the supervision of notified bodies: Criteria to be met for the designation of NB

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| Joint Audits of NBs by Designating Authority, Commission (FVO) plus two other CAs | • NBs and Designating Authorities under scrutiny  
• Highlights different approaches in Member States  
• More scrutiny of competency requirements, in-house clinicians, qualifications  
• Processes and procedures clarified  
• 15 NB audits to date: 10 NBs to withdraw! |
| NB Designation valid for a maximum of five years | • No impact yet; will need CA resource  
• Consistent with CE certification cycle |
| Extensions and Renewals follow the same procedure as Designations | • Helps consistency; will need CA resource |
| NBs subject to renewal by 14 October 2016 | • Helps consistency; requires CA resource |
| Designating Authorities shall have sufficient number of competent personnel | • Have they the qualified resource to deliver? |
Impact of Com. Recommendation (2013/473/EU) on audits and assessments performed by NBs – Items to be verified by NB during an audit

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| Annex I: Criteria for NBs performing design dossier and type examinations    | • Mainly reinforcement of current good practice  
• Increased need for clinical studies, less reliance on equivalence argument  
• Will clarify time needed for reviews                                           |
| Annex II: Criteria for NBs performing QMS assessments                        | • Mainly reinforcement of current good practice                                                                                       |
| Annex III: Unannounced visits to manufacturers, "critical subcontractors" or "crucial suppliers", in addition to planned audits | • Completely new requirement needing extra product and QMS assessors  
• Significant increase in NB workload and resources  
• IAF rules require planned audit schedules so no scope for substitution  
• A few issues to iron out (see Vicky Medley presentation)                       |
Overview

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- Impact of Proposed Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR): look at Commission examples
  - Pre-market control of high-risk devices
  - Designation, monitoring and functioning of notified bodies
  - Reprocessing of single-use medical devices
  - Borderline products
- Current Understanding of Regulatory Timetable
Pre-market control of high-risk devices

✓ Proposals made by the **European Parliament: case-by-case assessment by the Medical Devices Coordination Group** (‘MDCG’), assisted by a committee of scientific experts, focused on clinical aspects.

✓ Divergent positions of **Member States**.

✓ **Commission: scrutiny mechanism** important.

- Focus on thorough rigorous oversight of NB designation to maintain good competency and consistent interpretation
- Audit NB decisions and undertake benchmarking exercises routinely and on specific issues of concern
- If MDCG enrol three clinicians to look at a device, NBs will get three clinicians
- Longer timelines, increased uncertainty and cost will reduce innovation and benefit to the patient
Designation, monitoring and functioning of Notified Bodies

✓ **Parliament and Council**: good proposals to strengthen the designation, monitoring and functioning of notified bodies.

✓ **Parliament**: separate designation of "Special Notified Bodies" competent for high-risk devices by the European Medicines Agency (‘EMA’).

✓ **Commission**: need to *carefully assess* the added value of EMA involvement, as well as the necessary resources and financing.

- The proposals to strengthen the designation, monitoring and functioning of notified bodies in the MDR, IVDDDR and Immediate Action Plans are working. Support and build on them.

- “Special NBs” are full scope NBs under the current terminology. Two tier approach would cause confusion and needless redundancy.

- Would not EMA just provide a secretariat and use member state technical resource anyway?
Reprocessing of single-use medical devices

- **Proposals made by the European Parliament:**
  - All medical devices are considered suitable for reprocessing and reusable;
  - Reprocessor must provide scientific evidence;
  - Commission to adopt standards for reprocessing;
  - Possibility for Member States to ban the practice on their territory;
- **Diverging views between Member States**
- **Commission:** Commission proposal balanced approach

- Thorny area
- Commission proposal states that re-processors assume the obligations of CE markers of the device
- Can healthcare institutions or re-processors do this realistically without the co-operation of the original manufacturer?
- It is not just a case of a QMS assessment
Borderline products

✓ **Case C-109/12, Laboratoires Lyocentre v Lääkealan turvallisuus, 3 October 2013:**
  the qualification of a product as a medical device in one Member State does not preclude it from being qualified, in another Member State, as a different product;

✓ **Elements in the COM proposals aiming to ensure a more uniform implementation of the legislation:**
  - the Commission may decide, by implementing acts;
  - group of experts;
  - classification rule 21.

- Notified Bodies yearn for more uniform implementation of the legislation
- Minimises “notified body shopping”
- There is a need for a more efficient approach to making these decisions
- . . And also for making decisions to harmonise or change classifications of devices when new evidence appears
- Implementing acts centralise decisions and some member states are not happy
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Regulatory Timetable 1

#1 Commission proposal

26 September 2012:
- Commission proposal for a Regulation on medical devices
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#2 1st reading in the Parliament

April 2014 Parliament proposed amendments

#3 1st reading in Council

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Italian Presidency: Council reviewing proposal and EP amendments – two views:
1. Italians pushing hard for political agreement by end of 2014; talking informally to Commission and Parliament to get a proposal Parliament can accept at second reading; Latvians will get agreement first half 2015
2. Member states are so far apart that they will return the proposal with a number of clauses the Parliament will find difficult
Regulatory Timetable 2

Optimistic View
- First half 2015

Realistic View?
- Agreement in Dutch Presidency first half 2016
Regulatory Timetable: Pessimistic Scenario

• #6 Conciliation
  • The Conciliation Committee, composed of an equal number of MEPs and Council representatives, tries to reach agreement on a joint text. If unsuccessful, the legislative act will not enter into force and the procedure is ended. If a joint text is agreed, it is forwarded to the European Parliament and Council for a 3rd reading.

• #7a 3rd reading in Parliament
  • The European Parliament examines the joint text and votes in plenary. It cannot change the wording of the joint text. If it rejects it or fails to act on it, the act is not adopted and the procedure is ended. If it is approved by Parliament and Council, the act is adopted.

• #7b 3rd reading in the Council
  • Council examines the joint text. It cannot change the wording. If it either rejects or does not act on it, act will not enter into force and the procedure is ended. If it approves the text and the Parliament also approves it, the act is adopted.

• Proposal adopted
  • Once both European Parliament and Council have approved the final text of a legislative proposal, it is jointly signed by the Presidents and Secretaries General of both institutions. After signature, the texts are published in the Official Journal and become official.
    • Regulations are directly binding throughout the EU as of the date set down in the Official Journal

• Proposal not adopted
  • If a legislative proposal is rejected at any stage of the procedure, or the Parliament and Council cannot reach a compromise, the proposal is not adopted and the procedure is ended. A new procedure can start only with a new proposal from the Commission.
Conclusions

• Some serious differences between members states
• But strong will to reach agreement
• Best case Q2 2015 with three year (MDR) or five year (IVDDDR) transition
• Realistic case Q1 2016 with three or five year transition
• Joint action plan already having serious impact on level of scrutiny of all players in the regulatory process
• Make sure your quality systems and technical documentation are in very good shape
• Make sure your Notified Body is in good shape and in it for the long haul
• Ask the team...
Thank you

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